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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 047714-5002-US 5141 10/018,691 01/13/2004 David M Long EXAMINER 9629 7590 02/08/2006 MORGAN LEWIS & BOCKIUS LLP BURKHART, MICHAEL D 1111 PENNSYLVANIA AVENUE NW ART UNIT PAPER NUMBER WASHINGTON, DC 20004 1633

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | |
|--|---|---|-------------|
| | 10/018,691 | LONG ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Michael D. Burkhart | 1633 | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence add | ress |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | l. ely filed the mailing date of this com D (35 U.S.C. § 133). | |
| Status | | | |
| 1) Responsive to communication(s) filed on | | | |
| • | -· action is non-final. | | |
| 3) Since this application is in condition for allowar | | secution as to the | merits is |
| closed in accordance with the practice under E | · | | |
| | , , , , , , , , , , , , , , , , , , , | | |
| Disposition of Claims | | | |
| 4) Claim(s) <u>1-11</u> is/are pending in the application. | | | |
| 4a) Of the above claim(s) is/are withdray | vn from consideration. | | |
| 5) Claim(s) is/are allowed. | | | |
| 6) Claim(s) is/are rejected. | | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) 1-11 are subject to restriction and/or e | election requirement. | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examine | r. | | |
| 10) The drawing(s) filed on is/are: a) acce | epted or b) objected to by the E | Examiner. | |
| Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | |
| Replacement drawing sheet(s) including the correcti | ion is required if the drawing(s) is obj | ected to. See 37 CFF | ₹ 1.121(d). |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTC | D-152. |
| Priority under 35 U.S.C. § 119 | | | • |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicati ity documents have been receive i (PCT Rule 17.2(a)). | on No ed in this National S | Stage |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | (PTO-413) ate | .152) |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to methods of producing extrachromosomal DNA and replicable nucleic acid elements.

Group II, claim(s) 11, drawn to an artificial chromosome comprising a *Pestalotiopsis* telomerase and a DNA encoding an enzyme selected from the group listed in the claim.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. Claims 1-4 and those claims dependent on them relate to methods for the production of extrachromosomal and replicable nucleic acid sequences. The subject matter of claim 11 is not linked with the other claims by any special technical feature. The telomerase of claim 11 is not present in claims 1-10, and the enzymes involved in the taxol production referred to in claim 11 do not necessarily have to be the same as those referred to in claims 1-4. Furthermore, the artificial chromosome of claim 11 does not have to be made in a *Pestalotiopsis* cell, which is required for the methods of claims 1-4.

Accordingly, Groups I-II are not so linked by the same or a corresponding technical feature as to form a single inventive concept.

A telephone call was made to Elizabeth Weimer on 2/3/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

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process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart Examiner Art Unit 1633

SCOTT D. PRIEBE, PH.D.

Srott D. Pricke